

**REMARKS**

Claims 40-42 and 44-52 are pending. Claims 1-39 and 43 have been cancelled.

**Oath or Declaration**

Applicants submit herewith a copy of the declaration filed in parent case 08/500, 917.

**Rejections under 35 U.S.C. §112, first paragraph**

The Examiner rejected claims 40-42 and 44-52 under 35 U.S.C. §112, first paragraph, alleging that Applicants did not have possession of the invention at the time of filing. In particular, the Examiner apparently requires the sequence of the Factor V mutation indicated by the polymorphism disclosed in Applicants' Specification. Applicants traverse the rejection.

Applicants disclose that a neutral polymorphism in the Factor V gene, which a skilled artisan would know is caused by a mutation in the Factor V gene, is linked with APC-resistance. The discovery that a mutation in the Factor V gene sequence is linked to APC resistance provides a significant approach for determining if an individual is predisposed to APC resistance and thrombosis generally. The precise mutation in the Factor V gene is not disclosed; however, the precise sequence is not required. Applicants submit that the detection in an individual of any mutation in the Factor V gene that would alter Factor V function would provide a method for determining if an individual is predisposed to developing APC resistance and thrombosis. Applicants submit that they are not claiming a particular mutant Factor V gene, nor are they claiming methods for detecting a particular Factor V gene mutation. Applicants disclose and describe on page 20 of the Specification the art known steps required for determining if a Factor V gene sequence in an individual contains a mutation - such methods have been well known to skilled artisans in this area for many years. Furthermore, the sequence of the Factor V gene is well known. Applicants respectfully submit that their Specification need not reiterate methods that are well known in the art in order to comply with 35 U.S.C. §112, first paragraph.

**CONCLUSION**

Applicants respectfully urge that all claims are in condition for allowance and request prompt and favorable action on the instant application. If the Examiner believes that a telephonic interview with the undersigned would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned at (617) 310-8168.

Respectfully submitted,

  
Diana M. Steel  
Attorney for Applicant  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110

Date: October 10, 2003  
Reg. No. 43,153

Tel. No.: (617) 310-8168  
Fax No.: (617) 248-7100

2693670\_1